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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,083	05/23/2001	Mitchell S. Wortzman	01-40076-US	1801

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EXAMINER
KIM, VICKIE Y

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/864,083	WORTZMAN ET AL.	
	Examiner	Art Unit	
	Vickie Kim	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Application

1. Acknowledgement is made of reconsideration request for the pending claims filed 10/23/03. No amendment is filed.

2. The claims 1-23 are pending and presented for the examination.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1- 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon(US 5932612).

The claims 1-8 and 14-18 are drawn to a composition comprising hydroquinone(1-12%) and a cationic salt of acidic ascorbyl esters such as magnesium ascorbyl phosphate(0.1-3%) wherein said combination having pH of 5.5-8.

Gordon teaches a skin lightening composition for the treatment of hyperpigmentation comprising a dermally available derivative of ascorbic acid such as magnesium ascorbyl phosphate(0.05-10%, see claims 13-17), hydroquinone(1.5-4%, see claim 1 and col. 2, lines 66-67).

As to the claims 9-10, Gordon teaches sodium bisulfite, see table 1 at col. 2.

Although Gordon does not teach specific pH(i.e. 5.5-8) of the patented composition; sodium metabisulfite(required by the instant claims 11-13, 19-20) or aminopropyl ascorbyl phosphate or sodium ascorbyl phosphate(required by the instant claim 21-23), it would have been obvious to one of ordinary skill in the art to modify the

pH of the patented composition into about 5.5-8 because it is conventional knowledge that skin irritation is least caused when the pH of the composition is closest of the physiological pH that is about 7-7.5 and thus, it is ideal that the skin product has the pH of about 7-7.5. Or the substitution of sodium bisulfite(Gordon's) to sodium metabisulfite, or magnesium ascorbyl phosphate(Gordon's) with aminopropyl ascorbyl phosphate or sodium ascorbyl phosphate is also considered to be obvious to the ordinary skilled artisan because it is conventionally known(as evidenced by numerous documents, see PTO-892) that these species are functional equivalent to each other where one could reasonably expect the same result by substituting one to the other because they have similar chemical structure and same core structure that is responsible for the same effectiveness).

One would have been motivated to do so, with reasonable expectation of success because it is always desirable to have extended species for the substition to make variety therapeutic modalities to improve patient's compliance by enhancing patient satisfaction and increasing the selection option. The techniques and skills required for making such substitution is conventional knowledge and standard, and well within the skills of ordinary artisan, and thus, the claimed subject matter is embraced by the scope of the patented invention and not patentably distinct over the prior art of the record.

Although the instant claims use the different names for the said ingredients than those taught in the cited references, these references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited reference.

Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

5. Claims 1- 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenback in view of Gordon(US 5932612).

The text of those in this action can be found in a prior Office action.

Response to Arguments

1. Applicant's arguments filed 10/23/03 have been fully considered but they are not persuasive. Thus, the previous art rejections are maintained and all the claims are included in the same rejection.

2. Applicant argues that Gordon and Lukenback in view of Gordon fail to establish a prima facie case of obviousness because each patentee does not teach or suggest all the claim limitations of claim 1, and thus, Gordon or Lukenbak in view of Gordon cannot render obvious claims of the present invention.

Gordon

In response to applicant's argument, the examiner would like to emphasize the conventional wisdom that skin irritation is considered to be a primary concern in the dermatological/ pharmaceutical/cosmetic industry because said skin irritation often become a major reason for the drawback or failure. It is conventional knowledge

commonly known to the ordinary skilled artisan that too low or high pH of final product directly triggers unwanted skin irritation, where the physiological pH (about pH=7) is often considered to be an ideal pH for those dermatological and/or cosmetic products unless a. As mentioned in Gordon's patent(see abstract), the patentee's major concern is the reduction of the skin irritation during the hyperpigmentation treatment. Gordon teaches a topical composition effectively used in said treatment comprising hydroquinone and a cationic salt of acidic ascorbyl esters(i.e. magnesium ascorbyl phosphate), see claims 1-2 and column 2. Since Gordon(patentee) does not specifically mention about the pH of the patented composition, It is considered to be inherent characteristic where the pH of the patented composition would not cause skin irritation(physiologically compatible), or considered to be a minor variation that could be practiced easily within the skilled level of the ordinary artisan. It would have been obvious to one of ordinary skill in the art to conclude that the patented composition is physiological pH compatible and thus, the pH of the patented composition would have been near physiological skin pH(about 7) which would not trigger skin irritation. Otherwise, the pH should have been mentioned in the said patent since it is directly conflicted with patentee's primary concern.

In any event, the instant claims are broadly recited and simply require two structural components(i.e.hydroquinone and a cationic salt of acidic ascorbyl esters such as magnesium ascorbityl phosphate). The instant claims merely recites the physical characteristic of said composition where they have the pH of 5.5-8 without any further requirement. Since the instant claims fails to include particular inventive step to

modify the pH of the claimed composition, it is considered to be inherent characteristics or minor variation. Since the patented composition(Gordon's) also contains both critical components and both patentee and applicant have same concern, one of ordinary skill in the art presumably conclude that the patented composition would have possessed the same pH with the claimed composition. The said pH modification or the substitution between functionally equivalent species(e.g. sodium bisulfite with sodium metabisulfite; or magnesium ascorbyl phosphate with sodium ascorbyl phosphate or aminopropyl ascorbyl phosphate) is standard practice in the pharmaceutical industry to determine most effective and efficient treatment, as evidenced by numerous documents(US.

Thus, the burden of proof is on the applicant to show why the said pH modification or the said substitution is distinguished from the conventional knowledge and commpon practice.

Thus, the applicant's argument is not persuasive and the 103 rejection (unpatentable over Gordon's) is maintained.

Lukenbach et al in view of Gordon

Above references in combination make clear that hydroquinone and a cationic salt of acidic ascorbyl esters such as magnesium ascorbyl phosphate have been individually used for the treatment of hyperpigmentation. It is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in the prior art. The combination of active ingredient with the same character is merely the additive

effect of each individual component. *See In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).*

Declaration

In response to applicant's declaration filed 10/23/03, the declaration is irrelevant to the claimed subject matter because the claims require the combination of hydroquinone and a cationic salt of acidic ascorbyl esters such as magnesium ascorbyl phosphate. The composition of 100 B or 100C is based on the single ingredient not the combination. Thus, the declaration is fully considered but not persuasive.

> Evidence of unexpected properties may be in the form of a direct or indirect comparisin of the claimed invention with the closest prior art which is commensurate in scope with the claims. See in re Boesch, 617 F.2d 272, 205 USPQ 215(CCPA 1980).

Gordon teaches a combination composition of hydroquinone and a cationic salt of acidic ascorbyl esters such as magnesium ascorbyl phosphate that would be the closest of the claimed invention. If applicant wish to file the declaration, the unexpected result should be based on the relevant study, for instance, the pH of Gordon's combination composition is much different from that of the claimed invention, or the stability or therapeutic effectiveness of the claimed invention is unexpectedly superior than that of the Gordon's composition.

Conclusion

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

4. No claim is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Primary Patent Examiner
Art unit 1614